

### **REMARKS/ARGUMENTS**

Reconsideration of this application, in view of the foregoing amendment and the following remarks and arguments, is respectfully requested.

Claims 1-8 and 10-16 are currently pending in this application. By the foregoing amendment, Claim 1 has been revised. Accordingly, Claims 1-8 and 10-16 remain in this application for consideration and allowance.

In the January 6, 2009 Office Action the Examiner objected to Claim 1, requiring the insertion of the word --member-- after “first tubular” on line 2, and finally rejected Claims 1-8 and 10-16 under 35 USC §103(a) as being unpatentable over U.S. Patent 4,969,888 to Scholten et al in view of U.S. Patent 4,467,790 to Schiff, further in view of U.S. Patent 4,483,340 to Fogarty et al. Such objection and rejection are respectfully traversed for the following reasons.

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#### **1. The Objection to Claim 1:**

In the foregoing amendment the Examiner’s objection to Claim 1 has been overcome by inserting the word --member-- after the phrase “first tubular” on line 2 of Claim 1 as required by the Examiner.

#### **2. The Obviousness Rejection of Claims 1-8 and 10-16:**

Via amended independent Claim 1, each of applicants’ Claims 1-8 and 10-16 now specifies that applicants’ recited torque transmitting stylet longitudinally extends through the interior of the second tubular member and has a distal end **fixedly secured** to the distal end of the second tubular member. Representatively, but not by way of limitation, the claimed stylet is the stylet 52 shown in applicants’ FIGS. 4, , 7 and 8, the claimed second tubular member is the inner tubular catheter 18 shown in applicants’ FIGS. 4-8, with the hooked distal end 60 of the stylet 52 (see FIG. 6) being fixedly secured to the distal end of the inner tubular catheter 18 by means of adhesive bonding or heat bonding as set forth beginning on page 5, line 30 of applicants’ specification.

In the last paragraph on page 3 of the January 6, 2009 Office Action, the Examiner acknowledges that Scholten et al and Schiff fail to disclose the claimed structural limitations of the balloon device for causing wrapping and unwrapping of the balloon member (namely, applicant's previously claimed "torque transmitting stylet longitudinally extending through the interior of the second tubular member and having a distal end anchored to the distal end of the second tubular member").

The Examiner seeks to cure this deficiency in the Scholten et al and Schiff references using the disclosure in Fogarty et al of a core wire 30 which, via the removable mating of a non-circular distal end portion 32 thereof with a corresponding non-circular socket 34 formed in a solid tip member 22 on the distal end of an inner tubular member 24 as shown in FIGS. 2-4 of Fogarty et al, rotationally couples the core wire 30 to the balloon 20. It is the Examiner's position (see page 4 of the January 6, 2009 Office Action) that it would have been obvious to one skilled in the art at the time the invention was made to "construct the device of Scholten et al as modified by Schiff with the claimed structural limitations that allow for wrapping and unwrapping of the device in view of Fogarty et al in order to more easily deliver the expandable structure to a certain [area] within the body".

However, it should be noted that such a substitution would **not** provide, in the resulting structure, "a torque transmitting stylet longitudinally extending through the interior of the second tubular member and having a distal end **fixedly secured to** the distal end of the second tubular member" as now recited in each of the present applicants' Claims 1-8 and 10-16. This Examiner-proposed modification of a Scholten et al/Schiff combination using the teachings of Fogarty et al would yield a structure in which the core wire 30 was **removably secured to** a distal end portion of an inner tubular member.

In this regard, it is important to note that the Fogarty et al reference **requires** that the core wire 30 be **removable from** the inner catheter distal end portion 22. Specifically, it is stated in the Fogarty et al specification, beginning on 67 of column 2 thereof, that:

The combination of the core wire 30 and the flexible inner tube 24 provides the degree of rigidity or strength necessary to provide the relatively large initial torque which is required to start twist-retraction of balloon element 20. However, the rigidity or strength required in a core element to provide the needed degree of initial torque makes the balloon section of the catheter too stiff for

optimal movement of the catheter along a blood vessel. The wire 30 is made removable in this catheter so that the combined rigidity of the twisted balloon element and flexible tube 24 approximates the rigidity-flexibility characteristics of the balance of the catheter. Once the balloon element has been fully wound up and core wire 30 has been removed, the flexible tube 24 furnishes the lower value of torque which is required to keep the balloon element 20 in a wound-up condition.

The criticality in the Fogarty et al dilation catheter structure of this removability feature of the core wire 30 is further confirmed in the Fogarty et al specification, beginning on line 39 of column 1, wherein it is stated that:

In the present catheter this problem [i.e., the problem of a non-removable core wire directly affixed to a balloon element] has been overcome by providing the catheter with a pair of concentrically disposed balloon twisting elements. Both of the twisting elements are maintained in place while the balloon is being twisted. After the balloon has been twisted, one of the twisting elements is removed to thereby decrease the stiffness of the twisted balloon section of the catheter so that the balloon section has a flexibility comparable to that of the rest of the catheter.

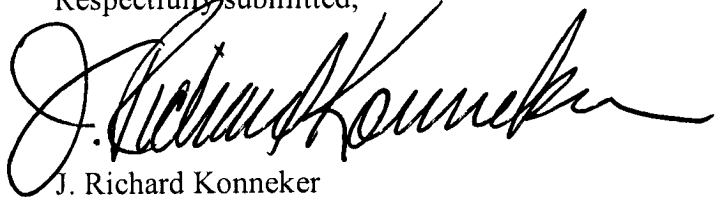
**The principal object of the invention is to provide a twist-type dilation catheter with a multiple component balloon twister, with part of the twister being removable to enhance the flexibility of the twisted balloon section of the catheter.** (Emphasis added).

It can thus be seen that even if the teachings of Fogarty et al were to be incorporated into the Scholten et al/Schiff combination as proposed by the Examiner, the limitations of the present applicants' Claims 1-8 and 10-16 would not be met since Fogarty et al expressly teaches away from applicants' claim limitation of "a torque transmitting stylet longitudinally extending through the interior of the second tubular member and having a distal end fixedly secured to the distal end of the second tubular member". Applicants therefore respectfully submit that none of their Claims 1-8 and 10-16 is rendered obvious by U.S. Patent 4,969,888 to Scholten et al, U.S. Patent 4,467,790 to Schiff, and U.S. Patent 4,483,340 to Fogarty et al, whether these three references are considered singly or in any combination thereof.

In view of the foregoing amendment, remarks and arguments, all of the claims currently pending in this application are now seen to be in a condition for allowance. A Notice of Allowance of Claims 1-8 and 10-16 is therefore earnestly solicited.

The Examiner is hereby requested to telephone the undersigned attorney of record at 972/739-8612 if such would further or expedite the prosecution of the instant application.

Respectfully submitted,



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